

CHAPTER 6

EVALUATION OF THE EFFECTS OF THE RULE ON SMALL ENTITIES

This section considers the effects of the regulations on small businesses. Section 6.1 discusses EPA's requirements under the Regulatory Flexibility Act. Section 6.2 outlines EPA's initial assessment of small businesses in the sectors affected by the regulations. Section 6.3 describes the EPA's compliance with RFA requirements and Section 6.4 presents the analysis of economic impacts to small entities that are affected by the final regulation.

6.1 THE REGULATORY FLEXIBILITY ACT AS AMENDED BY THE SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

The Regulatory Flexibility Act (RFA, 5 U.S.C et seq., Public Law 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) generally requires an agency to prepare a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. This is required of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a "significant impact on a substantial number of small entities." Small entities include small businesses, small organizations, and governmental jurisdictions. The RFA acknowledges that small entities have limited resources and makes it the responsibility of the regulating Federal agency to avoid burdening such entities unnecessarily. If, based on an initial assessment, a regulation is likely to have a significant economic impact on a substantial number of small entities, the RFA requires a regulatory flexibility analysis.

In addition to the preparation of an analysis, the RFA, as amended by SBREFA, imposes certain responsibilities on EPA when the Agency proposes rules that might have a significant impact on a substantial number of small entities. These include requirements to consult with representatives of small entities about the proposed rule. The statute requires that, where EPA has prepared an initial regulatory flexibility analysis (IRFA), the Agency must convene a Small Business Advocacy Review (SBAR) Panel for the proposed rule to seek the advice and recommendations of small entities concerning the rule. The panel is composed of employees from EPA, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Office of Advocacy of the Small Business Administration (SBA).

EPA is certifying that this final regulation will not have a significant economic impact on a substantial number of small entities. Despite this determination, EPA has prepared an evaluation of the effects on small entities that examines the impact of the rule on small entities along with regulatory alternatives that could reduce that impact. EPA also prepared an economic analysis of the potential impacts to affected small businesses. For the 2002 Proposal, EPA prepared an IRFA, which was published in the *Federal Register* (USEPA, 2002a; see FR 67: 57916-57917) and presented as part of the Economic and Environmental Impact Analysis (EEIA) for the proposed rule (USEPA, 2002b).

6.2 INITIAL ASSESSMENT

Prior to the 2002 Proposal, EPA conducted an initial assessment according to Agency guidance on implementing RFA requirements (USEPA, 1999). First, EPA must indicate whether the proposal is a rule subject to notice-and-comment rulemaking requirements. EPA determined that the proposed regulation is subject to notice-and-comment rulemaking requirements. Second, EPA should develop a profile of the affected small entities. EPA has developed such a profile of the aquaculture industry, which includes all affected operations as well as small businesses. This industry profile is provided in the Proposal EEIA (USEPA, 2002b, Chapter 2). Third, EPA's assessment needs to determine whether the rule would affect small entities and whether the rule would have an adverse economic impact on small entities.

For the proposed rulemaking, EPA concluded that costs are sufficiently low to justify "certification" that the regulations would not impose a significant economic impact on a substantial number of entities (USEPA, 2002a; see FR 67: 57916). In addition, however, EPA also complied with all RFA provisions and conducted outreach to small businesses, convened an SBAR Panel, and prepared an IRFA. That analysis described EPA's assessment of the impacts of the proposed regulations on small businesses in the aquaculture industry. A summary of this analysis was published in the *Federal Register* at the time of publication of the 2002 Proposal (USEPA, 2002a; see FR 67: 57916-57917). More detailed information on EPA's IRFA is provided in the Proposal EEIA (USEPA, 2002b, Section 8.3). EPA's Proposal EEIA also describes other requirements of EPA's initial assessment of small businesses and summarizes the steps taken by EPA to comply with the RFA (USEPA, 2002b, Section 8.4).

6.2.1 Definitions of a Small Aquaculture Entity

The RFA/SBREFA defines several types of small entities, including small governments, small organizations, and small businesses.

A "small governmental jurisdiction" is defined as the government of a city, county, town, school district, or special district with a population of less than 50,000. For the purposes of the RFA, Federal, State, and Tribal governments are not considered small governmental jurisdictions (USEPA, 1999).¹ Federal facilities, regardless of their production levels, are not part of small governments. EPA identified no public aquaculture facilities belonging to small governments that are affected by the rule. EPA identified one small organization, an Alaska nonprofit, within the scope of the rule.

The Small Business Administration (SBA) sets size standards to define whether a business entity is small and publishes these standards in 13 CFR 121. The standards are based either on the number of employees or annual receipts. Table 6-1 lists the North America Industry Classification System (NAICS) codes potentially in scope of the proposed rule and their associated SBA size standards as of January 1, 2002 (SBA, 2000 and SBA, 2001).

¹ See Section 9 of this report where impacts on these entities are summarized in accordance with Unfunded Mandates Reform Act (UMRA) requirements.

Table 6-1
Small Business Size Standards

NAICS Code	Description	Size Standard (Annual Revenues)
112511	Finfish Farming and Fish Hatcheries	\$0.75 million
112519	Other Animal Aquaculture	\$0.75 million

When making classification determinations, SBA counts receipts or employees of the entity and all of its domestic and foreign affiliates (13 CFR.121.103(a)(4)). SBA considers affiliations to include: stock ownership or control of 50 percent or more of the voting stock or a block of stock that affords control because it is large compared to other outstanding blocks of stock (13 CFR 121.103(c)); common management (13 CFR 121.103(e)); and joint ventures (13 CFR 121.103(f)).

EPA assumes the following for its evaluation:

- Sites with foreign ownership are not small (regardless of the number of employees or receipts at the domestic site).
- The definition of small is set at the highest level in the corporate hierarchy and includes all employees or receipts from all members of that hierarchy.
- If any one of a joint venture's affiliates is large, the venture cannot be classified as small.

6.2.2 Number of Small Businesses Affected by the Final Regulation

Based on detailed questionnaire data, EPA identified 37 facilities belonging to small businesses. It is quite possible for a small facility to belong to a large business, but a large facility—by definition—must belong to a large business.

6.2.3 Results of the Initial Assessment for the 2002 Proposal

For past regulations, EPA has often analyzed the potential impacts to small businesses by evaluating the results of a costs-to-sales test, measuring the number of operations that will incur compliance costs at varying threshold levels (including ratios where costs are less than 1 percent, between 1 and 3 percent, and greater than 3 percent of gross income). EPA conducted such an analysis at the time of the 2002 proposal, indicating that roughly 30 percent of the estimated number of small businesses directly subject to the rule might incur costs in excess of three percent of sales.

EPA's initial assessment at proposal covers facilities that produce more than 100,000 lbs/yr and met SBA's small business definition, consisting of 36 commercial facilities and 12 Alaska facilities (belonging to 8 nonprofit organizations). The results of this initial assessment indicate that 17 of 36 commercial facilities failed the 1 percent sales test (cost-to-sales ratio) and 10 of 36 commercial facilities

failed the 3 percent sales test. The maximum cost-to-sales ratio among these facilities was 7 percent. Among the Alaska nonprofit organizations, 3 of 6 facilities failed a 1 sales test, and 1 of 6 facilities failed the 3 percent sales test. A summary of this analysis was published as part of the proposed rule (USEPA, 2002a; see FR 67: 57916-57917), with more detailed information provided in the Proposal EEIA (USEPA, 2002b, Section 8.3).

6.3 RFA _____ AND SBAR PANEL

6.3.1 Outreach and Small Business Advocacy Review

EPA's engaged in outreach activities and convened a SBAR Panel to obtain the advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The Agency convened the SBAR Panel on January 22, 2002. Members of the Panel represented the Office of Management and Budget, the Small Business Administration and EPA. The Panel met with small entity representatives (SERs) to discuss the potential effluent guidelines and, in addition to the oral comments from SERs, the Panel solicited written input. In the months preceding the Panel process, EPA conducted outreach with small entities that would potentially be affected by the Agency's CAAP regulation. On January 25, 2002, the SBAR Panel sent some initial information for the SERs to review and provide comment. On February 6, 2002 the SBAR Panel distributed additional information to the SERs for their review. On February 12 and 13, the Panel met with SERs to hear their comments on the information distributed in these mailings. The Panel also received written comments from the SERs in response to the discussions at this meeting and the outreach materials. The Panel asked SERs to evaluate how they would be affected and to provide advice and recommendations regarding early ideas to provide flexibility. See Section 8 of the Panel Report for a complete discussion of SER comments. The Panel evaluated the assembled materials and small-entity comments on issues related to the elements of the IRFA. A copy of the Panel report is included in the docket for this proposed rule (see DCN 31019). EPA provided responses to the Panel's most significant findings as part of the proposed rule (USEPA, 2002a, 67: 57918-57920).

6.4 EVALUATION OF EFFECTS ON SMALL ENTITIES

EPA is certifying that this final regulation will not have a significant economic impact on a substantial number of small entities. EPA has evaluated the effects of the final rule on small entities, however, this review examines the impact of the rule on small entities along with regulatory alternatives that could reduce that impact. EPA's conclusions about potential impacts to affected small business of this rule are presented in Section 6.5.

6.4.1 Need for and Objectives of the Final Regulation

EPA is considering this action because aquaculture facilities may introduce a variety of pollutants into receiving waters. Under some conditions, these pollutants can be harmful to the environment and have a negative impact on water quality (Fries and Bowles, 2002; Loch et al., 1996; and Virginia, 2002). According to USDA's *1998 Census of Aquaculture*, there are approximately 4,000 commercial aquatic animal production facilities in the United States (USDA, 2000). Aquaculture has been among the fastest-growing sectors of agriculture until a recent slowdown that began several years ago. EPA analysis

indicates that many aquaculture facilities have treatment technologies in place that greatly reduce pollutant loads. However, in the absence of treatment, pollutant loads from individual facilities, such as those covered by the rule, can contribute substantial amounts of nitrogen, phosphorus, and TSS per year to the receiving water body. These pollutants can contribute to eutrophication and other aquatic ecosystem responses to excess nutrient loads and BOD effects.

Another area of potential concern relates to non-native species introductions from aquaculture facilities, which may pose risks to native fishery resources and wild native aquatic species from the establishment of escaped individuals (Hallerman and Kapuscinski, 1992; Carlton, 2001; Volpe et al., 2000; Leung et al., 2002; and Kolar and Lodge, 2002). Aquaculture facilities also employ a range of drugs and chemicals used therapeutically that may be released into receiving waters. For some investigational drugs, as well as for certain application of approved drugs, there is a concern that further information is needed to fully evaluate risks to ecosystems and human health associated with their use in some situations (USEPA, 2002a). Finally, aquaculture facilities also may inadvertently introduce pathogens into receiving waters, with potential impacts on native biota. This final regulation addresses a number of these concerns. These regulations are proposed under the authority of Section 301, 304, 306, 308, 402, and 501 of the Clean Water Act, 33 U.S.C.1311, 1314, 1316, 1318, 1342, and 1361.

6.4.2 Significant Comments in Response to the IRFA

EPA responded to significant comments on the proposed rule and its initial regulatory flexibility analysis in the Notice of Data Availability (USEPA, 2003). The majority of these comments express concern over the ability of regulated facilities to absorb additional operating costs due to regulation, given that USDA's *1998 Census of Aquaculture* reports that over 96 percent of trout farms are small businesses. USDA's comparatively high estimate of the number of small farm businesses is due to differences between USDA's and SBA's definition. For example, SBA's size standards differ from the revenue cutoff generally recognized by USDA, which has set \$250,000 in gross sales as its cutoff between small and large family farms (USDA, 1998).

EPA responded by using the detailed questionnaire data to capture revenue information at the facility and company level in order to identify small businesses; however, EPA continues to use SBA's small business definition per its guidance on how to comply with RFA/SBREFA requirements. EPA also presents a more thorough discussion of some of the other issues raised in public comments by conducting additional sensitivity analyses (e.g., cash flow, depreciation, sunk costs, capital replacement, and unpaid labor and management). See Appendix A for a more complete discussion of these topics.

6.4.3 Description and Estimate of Number of Small Entities Affected

Based on the information collected in its detailed questionnaire. Of the 38 facilities identified by EPA one is a noncommercial hatchery belonging to an Alaskan non-profit and 37 are commercial facilities belonging to small businesses. Of these, 36 are facilities in the Flow Through and Recirculating Subcategory and 2 are in the Net Pen Subcategory.

For the proposed rule, EPA stated its intention to make its final determination of the impact of the rule on small businesses based on analysis of detailed questionnaire data. However, EPA also convened a Small Business Advocacy Review Panel pursuant to RFA/SBREFA Section 609(b) (USEPA, 2002a, p.

2002a, p. 57909). For its 2003 Notice of Data Availability, EPA identified 117 facilities belonging to small businesses, seven facilities belonging to small organizations, and one academic/research facility among the facilities that produced more than 20,000 lbs/yr (USEPA, 2003). By restricting the scope of the rule to facilities that produce more than 100,000 lbs/yr, EPA also limited the number of small entities within the scope of the rule to 37 commercial facilities and one organization. The small business economic screening analysis for these 38 facilities is presented in Section 6.4.

6.4.4 Description of the Reporting, Recordkeeping, and Other Requirements

EPA's final rule includes a requirement for reporting Investigational New Animal Drugs (INADs) and extra-label use drugs, and a requirement to report failures and material damage to the structure of the aquatic animal containment system leading to a material discharge or pollutants. In addition to the BMP plan, the final regulation requires record keeping in conjunction with implementation of a feed management system. Flow through and recirculating facilities subject to the rule must record the dates and brief descriptions of rearing unit cleaning, inspections, maintenance and repair. Net pen facilities must keep the same types of feeding records as described above and record the dates and brief descriptions of net changes, inspections, maintenance and repairs to the net pens.

EPA estimates that each plan will require 40 hours per facility to develop the plan. The plan will be effective for the term of the permit (5 years). EPA assumed that each employee at a facility would incur a one time cost of 4 hours for initial BMP plan review. EPA included an annual cost for four hours of management labor to maintain the plan and eight hours of management labor and 4 hours for each employee for training and an annual review of BMP performance. EPA does not believe that the development and implementation of these BMPs will require any special skills. All of the CAAP facilities within the scope should currently be permitted, so incremental administrative costs of the regulation are negligible. However, Federal and State permitting authorities will incur a burden for tasks such as reviewing and certifying the BMP plan and reports on the use of drugs and chemicals. EPA estimated these costs at approximately \$13,176 for the three-year period covered by the information collection request or roughly \$4,392 per year.

6.4.5 Steps Taken to Minimize Significant Economic Impacts on Small Entities

EPA took several steps to minimize the potential impact of this final regulation. EPA restricted the rule in three major ways. First, EPA is restricting the rule to CAAP facilities rather than all facilities that raise aquatic animals. Second, EPA is restricting the scope of the rule to flow-through, recirculating, and net pen production systems. Third, EPA is restricting the scope to facilities that produce more than 100,000 lbs/yr. The USDA Census of Aquaculture identified approximately 4,000 aquaculture facilities nationwide (USDA, 2000). The final rule applies to an estimated 101 commercial facilities, approximately 2.5 percent of the total population.

Finally, EPA based the final rule on a technology option that has no adverse economic impacts on commercial facilities. While some commercial facilities may experience moderate impacts, EPA projects that no small businesses will close as a result of today's final rule. Given the results of this economic analysis of the effects on small businesses, EPA is certifying that this action will not have a significant economic impact on a substantial number of small entities.

6.4.6 Identification of Relevant Federal Rules that May Duplicate, Overlap, or Conflict with the Final Rule

Since the start of the rulemaking effort, Congress and Federal agencies have been working to clarify roles regarding the final CAAP regulation. EPA met with various stakeholders to ensure that other Federal rules would not duplicate, overlap, or conflict with the final rule.

EPA met with USDA's Animal and Plant Health Inspection Service (APHIS) to discuss how the requirements and objective of the CAAP rule relate to authorities under their jurisdiction (DCN 31123). At that meeting, USDA discussed how the Animal Health Protection Act (enacted as part of the 2002 Farm Bill), which gives APHIS the authority to develop and implement aquatic animal health programs. This law gives authority to APHIS for aquatic farm-raised animal disease management including emergency responses actions to invasive pathogen outbreaks. APHIS is also authorized to implement control programs using drugs or chemicals and biosecurity practices to reduce disease risk and impact on the industry. EPA and APHIS also discussed APHIS' broad mandate to address import and interstate movement of exotic species under the Federal Plant Pest Act and the Plant Quarantine Act.

EPA met with FDA to clarify FDA's environmental assessment requirements for the substances over which FDA has jurisdiction (DCN 31126). EPA and FDA are working on a formal agreement that would address environmental concerns about the discharge of drugs used at aquatic animal production facilities. This agreement, which might help protect the aquatic environment from harm, would facilitate information sharing about effluent concentrations of active drug ingredients. When appropriate, FDA would include in the labeling of approved new animal drugs, effluent concentrations of the active drug ingredient which should not be exceeded in wastewater discharges. EPA would notify permitting authorities who would incorporate these effluent concentrations into the NPDES permits as enforceable requirements.

6.5 EPA'S EVALUATION OF SMALL ENTITY IMPACTS

EPA's evaluation shows that the final rule will have no adverse economic impacts on commercial facilities, including small businesses. The results of EPA's economic analysis presented in Section 5.2 covers all regulated facilities, including both small business and businesses that do not meet SBA's small business definition. EPA projects no closures for facilities owned by small businesses. For the small organizations costs are less than 0.2 percent of salmon revenues.

EPA projects that this rule will have some moderate impacts on small businesses. One small business is projected to fail the credit test although no small companies undergo a change in financial status under the Financial Health Test described in Section 3.2.2.3 as a result of the rule. Four facilities belonging to small businesses have costs-to-sales ratios in excess of five percent. All four of these facilities are in the Flow Through and Recirculating Subcategory. No facilities have costs between 3 percent and 5 percent of sales.

6.6 REFERENCES

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